



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

Note to Reader
August 7, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

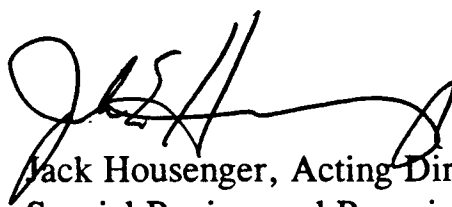
There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', with a long horizontal flourish extending to the right.

Jack Housenger, Acting Director
Special Review and Reregistration
Division

April 16, 1996

MEMORANDUM

SUBJECT: **PHORATE:** The HED Chapter of the Reregistration Eligibility Decision Document (RED), Case #0103, PC Code 057201

From: Jane Smith, Chemist /s/
Risk Characterization and Analysis Branch
Health Effects Division 7509C

Thru: Michael Metzger, Acting Branch Chief /s/
Risk Characterization and Analysis Branch
Health Effect Division 7509C
and
Stephanie Irene, Ph.D., Acting Director /s/
Health Effects Division 7509C

To: Jill Bloom
Special Review Branch
Special Review and Reregistration Branch 7508

The Human Health Assessment for the Reregistration Eligibility Document for phorate is attached. This chapter includes the Hazard Assessment from Yung Yang in Toxicology Branch II, the Occupational/Residential Exposure Assessment from Olga Odiott in OREB, the Dietary Exposure Assessment, Product Chemistry and Tolerance Reassessment from David Miller in Chemistry Branch II, and the Dietary Risk Assessment from Brian Steinwand in DRES.

The label recommendations and labeling rationales concerning the Worker Protection Standard for Sections IV and V of the RED will be addressed later when we are certain they are necessary.

Summary of Confirmatory Data Requirements / Label Changes / Significant Items

- 1) A combined reproductive-developmental neurotoxicity study is required.
- 2) Oral acute and subchronic studies in rats and a six month study in dogs, rabbits, or monkeys to determine ocular effects are required.
- 3) A neurotoxicity screening battery (acute and subchronic) is required. It should be noted this subchronic neurotoxicity study can be conducted in a combined reproductive-developmental neurotoxicity study of this chemical
- 4) Label amendments are required. The restriction against the feeding of sugar beet tops or silage to dairy cattle is considered impractical and should therefore be removed from labels for EPA Reg. Nos. 241-53, 241-145, and 241-257. In addition, a 30-day pregrazing interval has been established for at-cultivation applications to field corn to control chinch bug nymphs; this pregrazing interval should be extended to the at-cultivation application to field and sweet corn to control corn rootworms (EPA Reg. Nos. 241-53, 241-145, and 241-257).

5) HED concluded that a 12-month plantback restriction was appropriate for root and tuber vegetables, leafy vegetables, and cereal grains. There are currently no rotational crop restrictions on product labels.

6) No tolerances currently exist for field corn stover (fodder), sweet corn stover (fodder), sorghum forage, and wheat hay. Some field residue data have been submitted for these commodities; however, none of the available data reflect the currently registered use patterns for these crops. Therefore, additional field residue data are required for these commodities. In addition, Table II (in Subdivision O of the Pesticide Assessment Guidelines September, 1995) identifies cotton gin byproducts as a raw agricultural commodity of cotton; therefore, field residue data must be submitted for cotton gin byproducts. Tolerances must be proposed for these commodities when adequate field residue data have been submitted.

7) NO field residue data are available to support the use of phorate on field corn under SLNs OR840038 and WA840041 (broadcast aerial application prior to tassel emergence). The registrant for these SLNs is Platte Chemical Company. American Cyanamid does not wish to support this use pattern and SLNs registered to American Cyanamid with this use pattern were canceled by the registrant in response to data requirements imposed in the FRSTR. Unless Platte Chemical Company wishes to submit field residue data to support these use patterns, SLNs OR840038 and WA840041 should be canceled.

8) The greenhouse/nursery uses are not included in this assessment, since there are no such uses registered.

Should you have any questions, please let me know, by CC:Mail preferably.

cc: OOdiott (OREB), DMiller (CBTS), BSteinwand (DRES), YYang (TOX II), PDeschamp (RCAB), MHawkins (for Caswell, microfiche) jss:JSS:5/14/96.